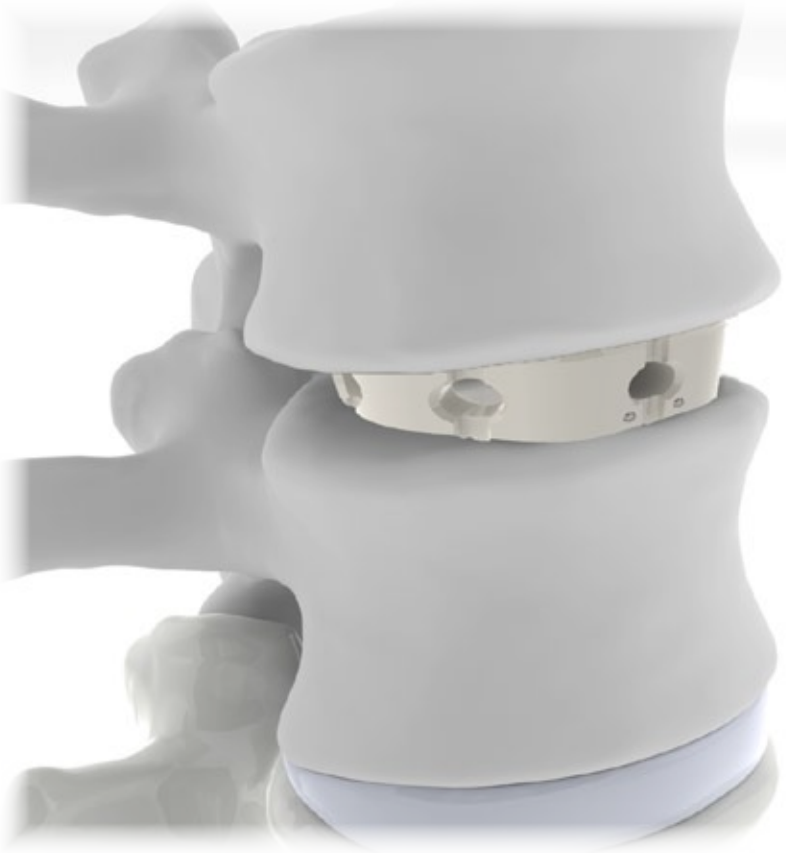


HumanTech
Smart German Solutions

ADONIS®

ANTERIOR LUMBAR INTERBODY FUSION

ALIF

ADONIS®-ALIF cages are indicated for anterior lumbar vertebral body fusion.
The implants are designed to be perfectly adapted to the anatomy of vertebral bodies in order to re-establish lordosis for reliable normalisation of the alignment of the spinal column and to provide stability and optimum conditions for fusion with the following indications:

- herniated discs
- calcified herniated discs
- mechanical instabilities
- calcification of the posterior longitudinal ligament
- osteochondrosis
- spinal canal stenosis

ADONIS®-ALIF iis an intelligent - and by virtue of the associated set of instruments - highly rational interbody device system and is a widely accepted product line offering the following decisive advantages:

Anatomy
- Geometry comparable with the patient‘s own sectional and sagittal anatomy
- Generous contact surface - reduced risk of migration

Stability
- Antegrade toothing for stable anchorage (not in all versions)
- Cranial convex contact surfaces for secure, permanent and high precision seating
- Significantly increased extraction forces
- Extremely high friction coefficient

Integrity
- Large filling aperture for rapid fusion (not in all versions)
- Internal annular groove holds the filling material in the cage and increases the filling volume

Modularity
Due to free choice among 3 materials:

• Titanium
The metal titanium has proved itself to be especially bio-tolerable and correspondingly modifiable. It has been proven that the various reactions of human cells are only caused by the oxidised surface layer of titanium materials, which is only a few nanometres thick.

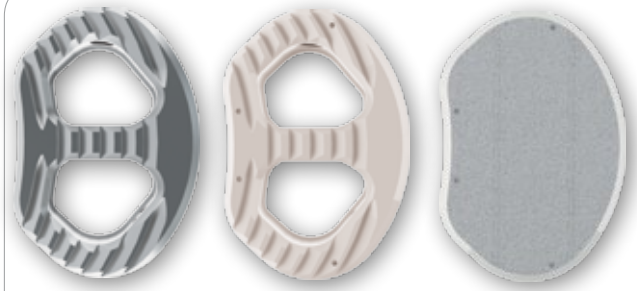
• PEEK
Our PEEK material has been tested as per ISO 10993, classified according to US P-VI, and FDA Device and Drug Master Files are available.

• PEEK titanium-coated
The titanium coating which, due to the balance between pore depth, porosity and roughness, affords an optimum substrate, has proven to be ideal for the docking of bone cells in the implant. The osteoinductive properties of titanium encourage bone to take root directly on the implant.

ADONIS® -ALIF

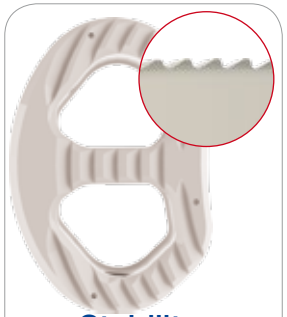
Interbody Device System

Product-Specific Advantages



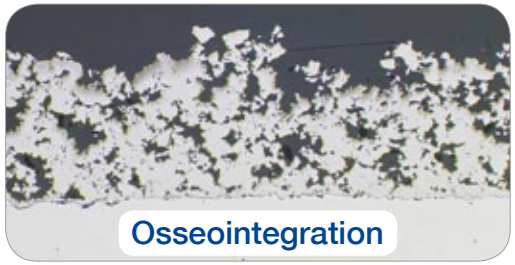
Modularity

Integrity

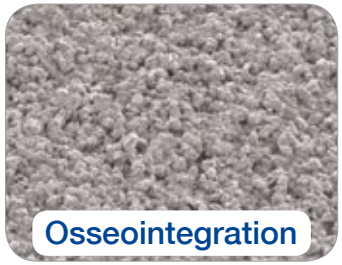


Stability

Anatomy



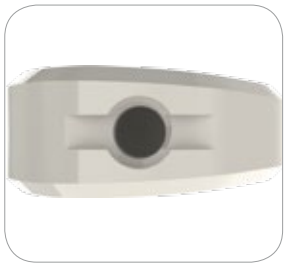
Osseointegration



Osseointegration

1. Modularity
2. Integrity
3. Stability
4. Anatomy
5. Osseointegration

Osseointegration



ADONIS®-ALIF Classic

ADONIS® Classic is a solid titanium interbody device system and is a generally accepted product line for thoracolumbar indications.
In combination with a tried & tested, intuitive set of instruments, ADONIS® Classic is the ideal solution for thoracolumbar interbody fusions.

The latest scientific findings are factored into the production of titanium implant materials with tailor-made surface properties. We exclusively use titanium Ti 6Al-4V ELI (as per DIN ISO 5832-3).

TITAN

ADONIS®-ALIF Avantgarde

ADONIS® Avantgarde is an implant made of biotolerable PEEK-Optima® for thoracolumbar interbody fusion and finds application in degenerative intervertebral disc disease and instability.

This material, which is radiotranslucent, enables rapid and straightforward assessment of the bone structure and fusion process. Positional verification is aided by X-ray markers. The mechanical rigidity of 3.6 GPa enables optimum force transmission between the implant material and the natural bone, thus stimulating the bone regeneration process.

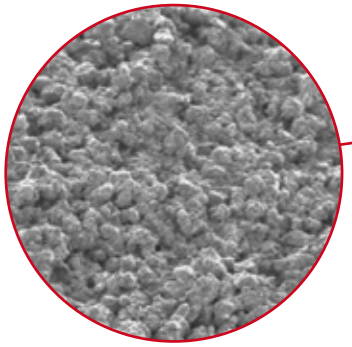
Our PEEK material has been tested according to ISO 10993 and classified as per USP-VI, the corresponding FDA Device and Drug Master Files are available. PEEK is predestined for use as an implant material because of its properties and usage authorisations.

PEEK

ADONIS® Exclusive

ADONIS® Exclusive is rewriting standards in the area of thoracolumbar interbody fusion.
The titanium coatings of the new ADONIS® Exclusive cages combine the advantages of various materials in one implant. The basis of the implant is a solid Peek core. This core is coated with titanium to increase the surface area and thus also to maximise the contact zone between the implant and the vertebral body surface.

PEEK Ti-coated

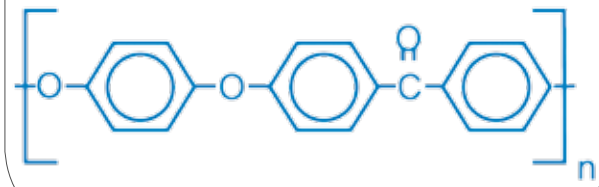


The titanium coating that, due to its balanced relationship between pore depth, porosity and roughness, affords an optimum substrate has proven to be ideal for docking bone cells in the implant. The osteoinductive properties of titanium encourage bone to take root directly on the implant.

Eigenschaften PEEK und PEEK Ti-coated

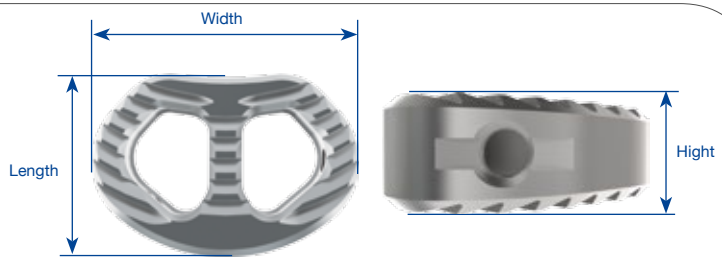
- PEEK is radiotranslucent and does not create any artefacts
- Positioning verifiable by means of X-ray markers
- Anatomical form and toothed or Ti-coated surface
- The semi-circular form maximises the contact zone
- It can optionally be filled with bone or bone replacement material for improved bone grafting in pure Peek cages
- Firm connection to the application instrument

PEEK-OPTIMA® is a polyaromatic, semicrystalline thermoplastic, based on the $(-C_6H_4-O-C_6H_4-O-C_6H_4-CO-)_n$ formula and generally known as a polyether ether ketone.



Classic

Titanium



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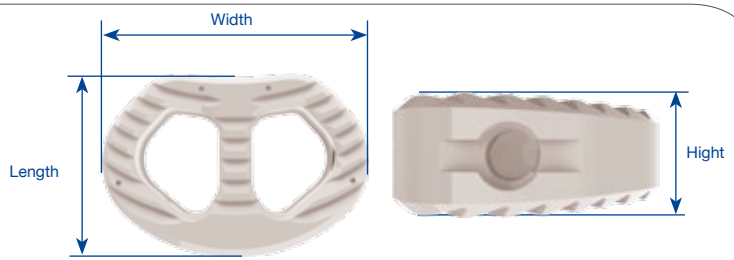
Avantgarde

PEEK



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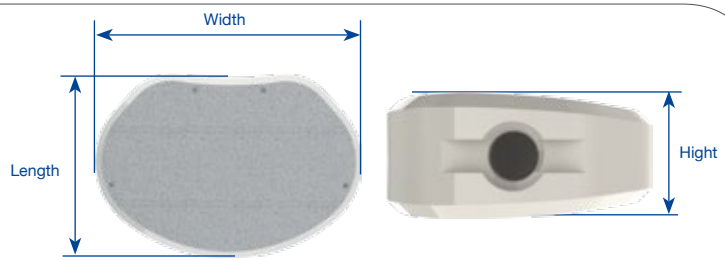
1902112209	Adonis ALIF PEEK 32x22x09 7°	32	22	9	7°
1902112211	Adonis ALIF PEEK 32x22x11 7°			11	
1902112213	Adonis ALIF PEEK 32x22x13 7°			13	
1902112215	Adonis ALIF PEEK 32x22x15 7°			15	

Exclusive

PEEK-Coated



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1903102209 1903102211 1903102213 1903102215	Adonis ALIF PEEK-Ti 32x22x09 7° Adonis ALIF PEEK-Ti 32x22x11 7° Adonis ALIF PEEK-Ti 32x22x13 7° Adonis ALIF PEEK-Ti 32x22x15 7°	32	22	9 11 13 15	7°

Instruments

ADONIS®-ALIF

Art.Nr.	Name	Image
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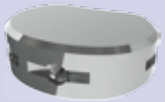
1901010709 1901010711 1901010713 1901010715	ALIF Trial 26x20x09 10° ALIF Trial 26x20x11 10° ALIF Trial 26x20x13 10° ALIF Trial 26x20x15 10°	
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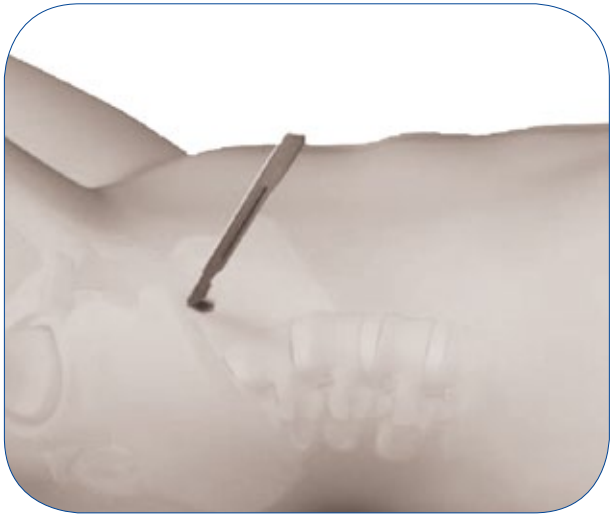


Fig. 1

Positioning of the patient

Anaesthetisation of the area and use of a small stab incision for the puncture.

Palpation of the anterior upper area of the iliac crest. The access point should be at least 2 cm laterally removed from the anterior upper iliac crest to avoid damage to the femoral cutaneous nerve.

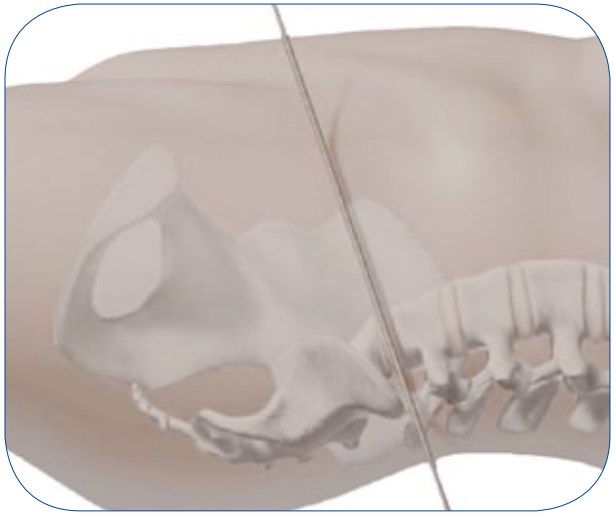


Fig. 2

Anterior approach

Surgical approach depends on the segment to be treated. The correct intervertebral disc level is identified by means of an image intensifier and a corresponding linear metal axis at the side of the patient. This ensures crisp delimitation of the intervertebral disc space on both sides of the vertebral body centre line.

Depiction of the vertebral disc segment to be operated on via standard retroperitoneal approach.

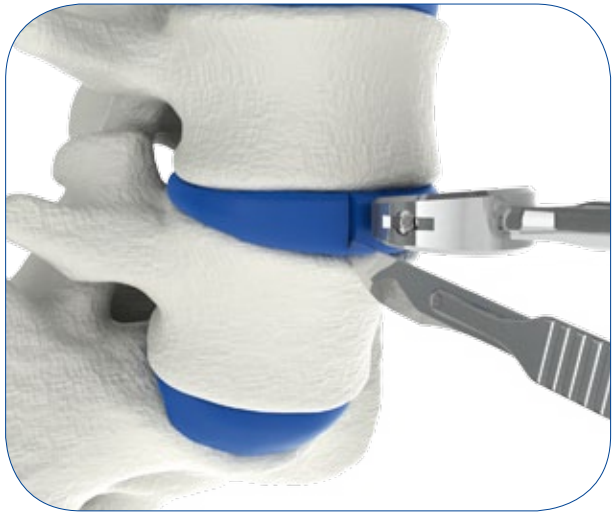


Fig. 3

Preparation of an anterior aperture

For the anterior approach, the intervertebral disc space is presented so that enough space is available in relation to the implant widths on both sides of the vertebral body middle line.
If it proves difficult to clear vessels and / or tissue to a sufficient extent, an anterolateral approach is recommended. Cut a rectangular aperture in the anterior longitudinal ligament and the fibrous ring, corresponding to the width of the ADONIS®-ALIF. The aperture width can be checked with a trial implant. Retain as much of the anterolateral, lateral and posterior annulus as possible in order to ensure the required stability of the operated on segment.

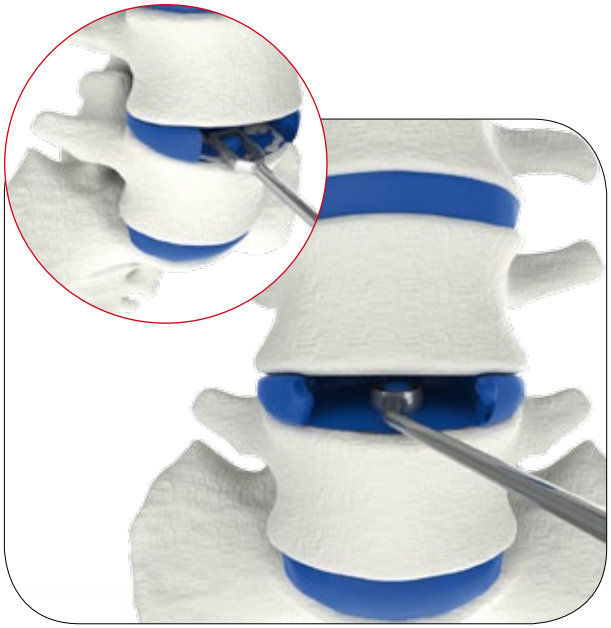


Fig. 4

Preparation of the intervertebral disc space

Remove the intervertebral disc material and the cartilaginous layer of the end plates to reveal the bond end plate structure. In order to supply the vessels with sufficient bone graft, it is important to ensure sufficient spacing of the end plates. Excess play or incorrect use of the rasp results in a weakening of the end plates and can lead to breach of the cage.

Note:
It is important that the nucleus and the inner annulus are removed to prevent a displacement of this material into the spinal canal during implantation and to avoid adversely affecting the bone ingrowth.

Fig. 5

Distraction

To ensure that the collateral impact of distraction is minimised, check the position of the retractor laterally with an image intensifier.

Distraction is essential for re-establishing the height of the intervertebral disc, the intervertebral foramen and the initial stability of the ADONIS®-ALIF.

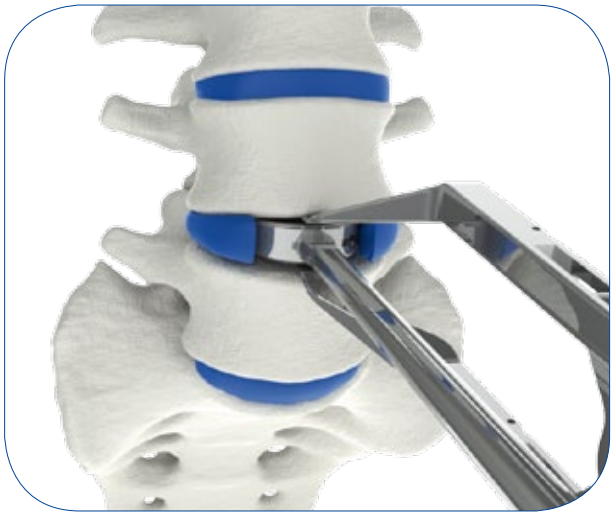


Fig. 6

Determination of the implant size

Select an appropriate test implant and fix it to the grip. The distractor can be used as a guide. In order to ensure that the implant is symmetrically introduced in the intervertebral space, the centre line of the distractor blades should therefore be aligned with the anterior centre line of the vertebral bodies. Push the trial implant by means of light hammer blows through the distractor blades. Use the next size, if the seating of the implant is not satisfactory. The trial implant must sit firmly when gently pressed in the intervertebral space. The intervertebral disc height may not decrease when the distractor is removed.

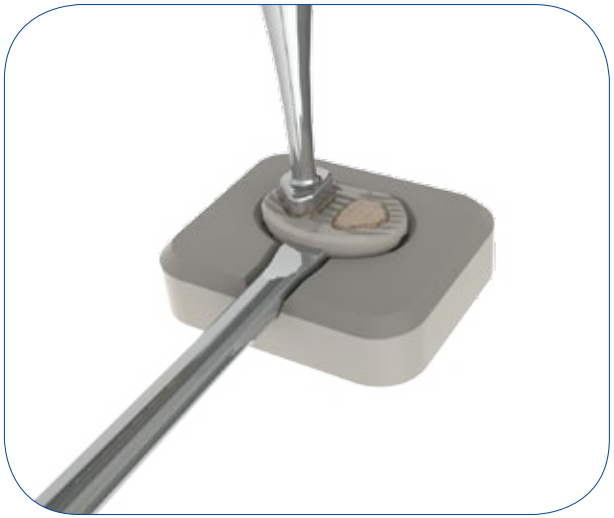


Fig. 7

Preparation of the implant

Select the trial implant in accordance with the ADONIS®-ALIF implant size. After the implant and the implant holder have been installed, the apertures are filled with a sufficient amount of bone graft by means of the impactor to create optimum contact with the end plates.

Note:
In order to avoid damage to the cage, the implant must be firmly attached to the implant holder.

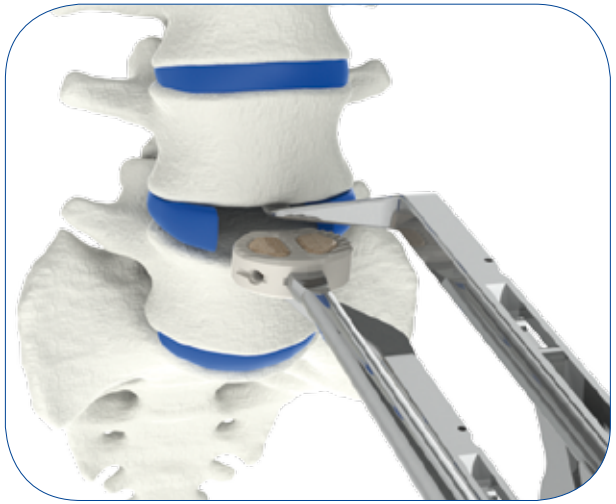


Fig. 8

Introduction of the implant

Slide the implant into the intervertebral space. The distractor can be used as a guide. To ensure that the implant is symmetrically introduced, the centre line of the distractor blades should be aligned with the anterior centre line of the vertebral bodies. Push the trial implant by means of gentle hammer blows through the distractor blades. The implant must be gently pressed into place in the intervertebral space.

Note:
To protect the adjacent structures, the distractor should remain in the intervertebral space during the entire manoeuvre.

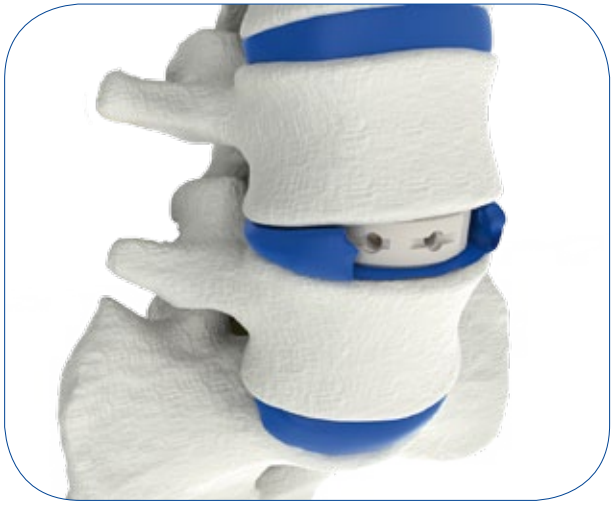


Fig. 9

Remove the instruments

After the implant has been correctly positioned, the distractor can be removed and the distraction can be ended.
Remove the distractor carefully, while the implant is held in position by the implant holder.
Now also carefully remove the implant holder, so that the implant remains in its optimum position.

Fig. 10

Checking the implant seating

The optimum implant seating is when the implant is exactly centred between the end plate boundaries.
Depending on the vertebral size, the anterior edge of ADONIS®-ALIF should be 3 mm from the anterior edge of the adjacent vertebrae.

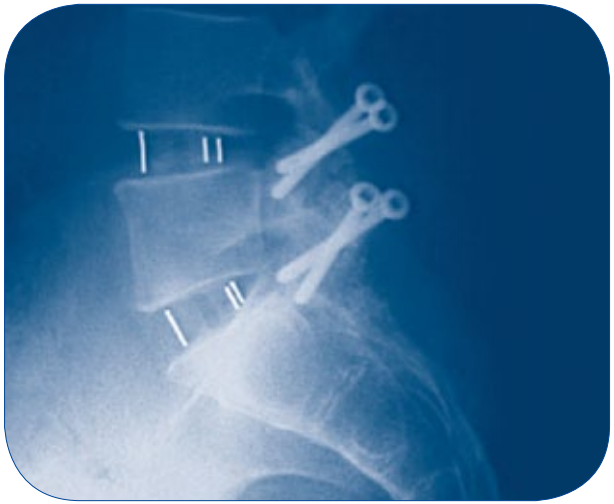


Fig. 11

X-ray examination

Examine the position of the cage in relation to the vertebrae in the anterior and lateral direction. The X-ray markers that are integrated in the implant mean that the position can be exactly determined intra-operatively by X-ray.

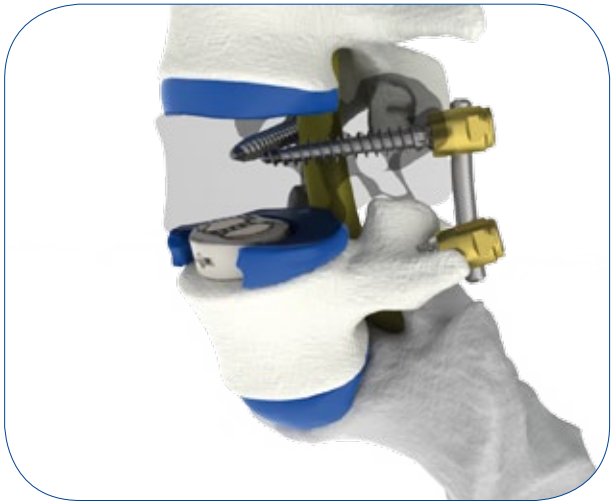


Fig. 12

Supplementary fixation

Determine the approach positions of the pedicle screws. The optimum position is at the intersection of the transverse process and the pars interarticularis.
The pedicle screws are implanted and their position verified by means of an X-ray image.

More information about the introduction of the pedicle screws is available in the respective operation manual for the utilised dorsal

The implant surface has a big importance for anchoring the implant and for the implant compatibility at the interface implant / adjacent tissue.
The success and speed of osseointegration are significantly influenced by the surface of the implant.
Using an ideal implant surface the biological responses between implant and bone can be optimized, and thus an earlier functional loading of implants can be achieved.

Immediately after introducing the implant there are induced complex biological processes between the surrounding tissue and the implant surface. The bone- and wound healing can be divided in 3 phases.

During the first and most important healing phase, the first blood contact builds a fibrin network (Fig 8) on the implant surface. This is connected with the aggregation of thrombocytes and blood coagulation.
The hereby emerging blood coagulum is an important matrix for the invasion and migration of osteogene cells to the implant surface and thereby plays a deciding role for wound healing and osseointegration.

The osteogene cells differentiate at the implant surface and activate the building of new bone through edifying a bone specific extracellular matrix (collagen) on the implant surface.

On the next step there is built a mineralized boundary surface. This is equivalent to a thin collagene-free coat on one osteon outer side in the natural bone tissue.

In the third, slow healing phase, the bone is reconstructed until reaching his final load-bearing characteristics.

The time required for the three phases of healing time is called osseointegration time and describes the time in which the bone substance links to the implant surface in a sufficient and permanent efficiency.

ADONIS® Exclusive has an optimized and reproducible surface-topography. The relation between surface-topography and successful osseointegration has been studied in the last three decades intensively and is well described today.

Beside the surface-topography, the osseointegration of the implant can be improved through chemical coatings on the surface. The moderately rough suface (Fig. 14 - „HENIAPORE-K“) of ADONIS® Exclusive leads to a better bone adherence.

HENIAPORE-K has been developed in order to optimize the implant surface in a way, fast and postoperative adherence of young bones is encouraged (Fig. 15). A review of clinical- and animal studies of Shalabi et Alvi affirms this statement.

Actually the vacuum-plasma-injection-procedure used for ADONIS® Exclusive is the most successful method in creating biocompatible surfaces. Due to this very extensive manufacturing process an optimum wettable implant surface is conserved while preserving the same surface topography.
The osseointegration can be accelerated through the improved wettablity and there

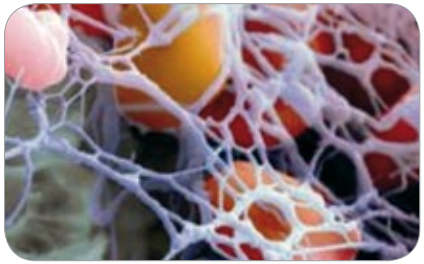


Fig. 13

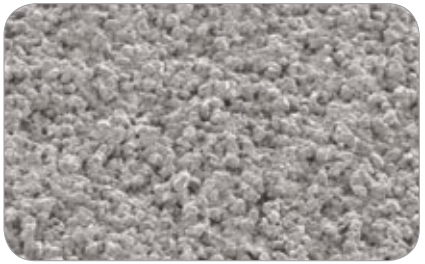


Fig. 14


Fig. 15

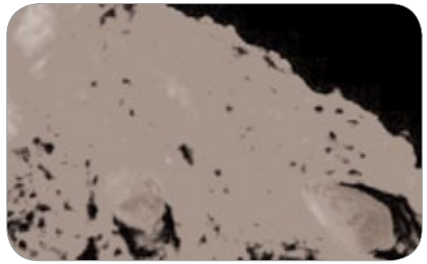


Fig. 16

is reached a higher implant stability at the early osseointegration phase, as is shown in clinical data and animal studies.

This method is globally proved for hip-, knee-, shoulder-, wrist- and tooth implants. The spinal application thus appears to be logical.

Nowadays commercially successful implant systems have an optimal and reproducible surface topography. Additional to those, ADONIS® Exclusive has an optimized and reproducible surface chemistry, which leads to an improved wettability and hereby a more homogenic blood contact with the implant surface.

The result of this is a faster implant osseointegration, facilitating an earlier load.

Summery

The long-term success of an implant therapy concept is determined by multiple factors, but mainly by the bone density of the implant bed, the implant design and implant surface.

The composition, roughness and topography of the implant surface at the interface are playing an important role for the primary stability and a safe osseointegration.

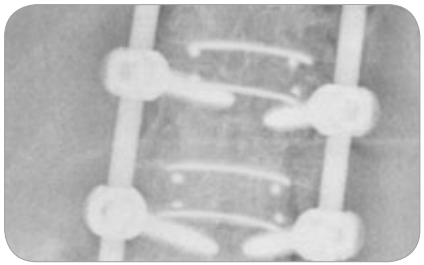
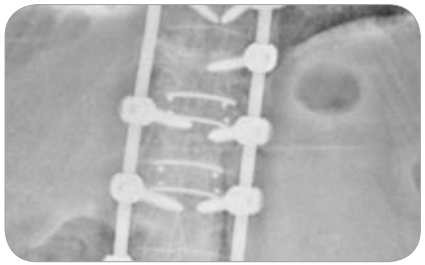
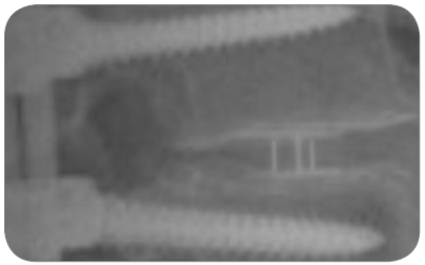
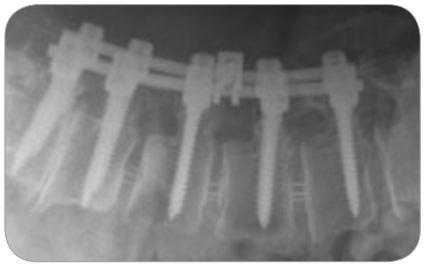
Rough implant surfaces will influence and stimulate the cellular activity of surrounding bony structures. The cell proliferation and cell differentiation, matrix synthesis and production of the „Tissue Growth Factors," are promoted and will lead to a dense bone-implant connection.

Specific surface roughness of the implant will promote the regeneration potential at the interface and thus the clinical implant fixation.

Compared to machined implant surfaces the moderately rough surface (Fig. 14 - „HENIAPORE-K") of ADONIS® Exclusive shows denser bone apposition with significantly increased withdrawal force (load removal) and an extremely high coefficient of friction for primary stabilization.

This results in an accelerated osseointegration of these implants and the possibility of an earlier exposure.

Attribute	Value
Roughness	Rz > 70
Coat thickness	50 -150µm
Coat porosity	> 20%
Adhesion	> 22 MPa
Shearing resistance	> 20 MPa

GENERAL CONDITIONS FOR USE

- We recommend that you do not use ADONIS® in combination with implants from another source or another manufacturer. HumanTech Germany GmbH is not liable if this recommendation is not followed.

- Never reuse the implants. Even if the implant appears to be intact following revision, alterations within the implant or minute defects resulting from the loading and stressing to which the implant has been subjected can cause the implant to break.

- Implants from the ADONIS® range have a limited useful life. The activities and physical activity of the patient have a significant influence on this useful life. The patient must be informed that every activity increases the risk of loss, bending or breakage of the implant components. Informing the patient about limitations to his or her activities in the postoperative phase and postoperatively monitoring the patient are decisive for assessing the development of the fusion and the condition of the implant. Even when permanent bone fusion has occurred implant components can still bend, break or loosen. It is therefore necessary to make the patient aware that implant components can also bend, break or become loosened when the patient limits his or her activities.

- In the event of implant breakage, the doctor must decide in view of the patient‘s condition and the risks which could occur whether to perform a revision of the implant.

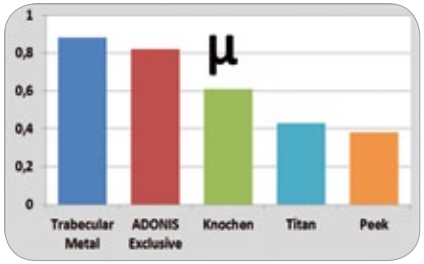
- Following the notes in the operating instructions (surgical technique) is essential.

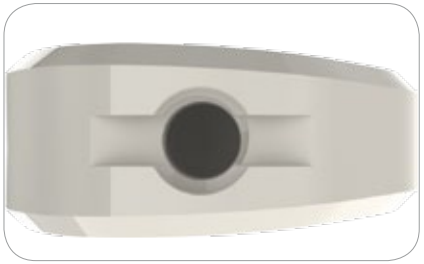
- Proceed with extreme caution in the region of the spinal cord and the roots of the nerves, since damage to the nerves can lead to the impairment of neurological functions.

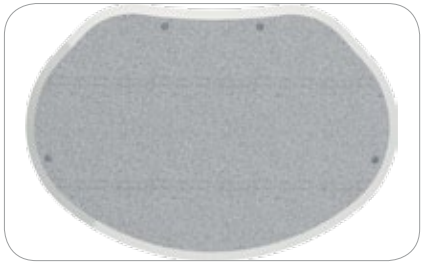
- Breakage, slippage or incorrect use of the instruments or implants can injure the patient or the operating staff.

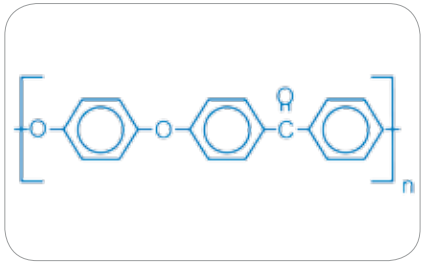
- Do not use bone cement, as this material makes the removal of the components difficult or impossible. The heat produced by the hardening process can damage or deform the PEEK implants.

- Handle removed implants in such a way that their reuse is not possible.

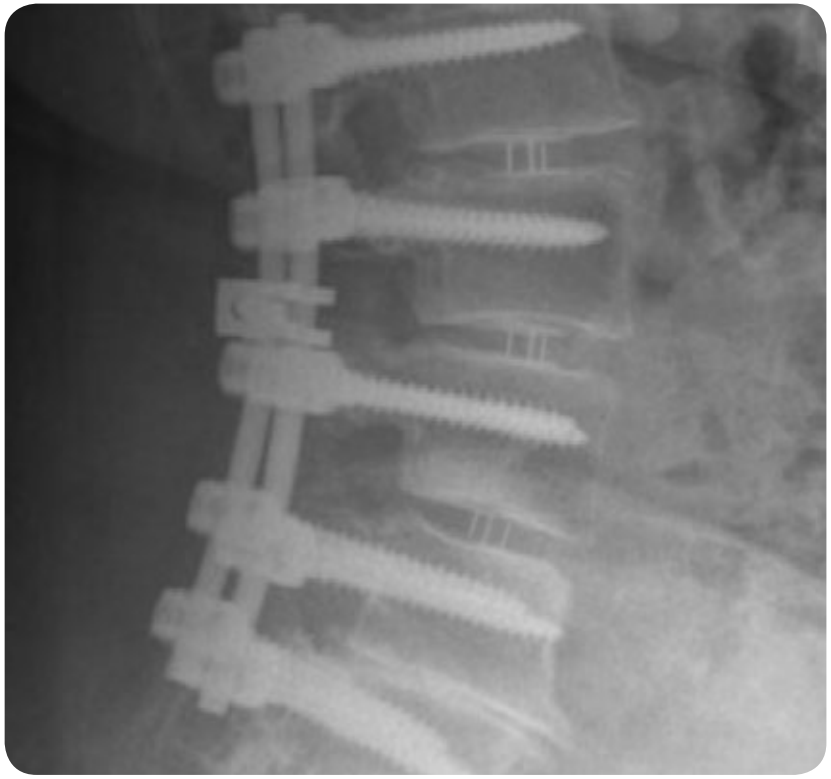


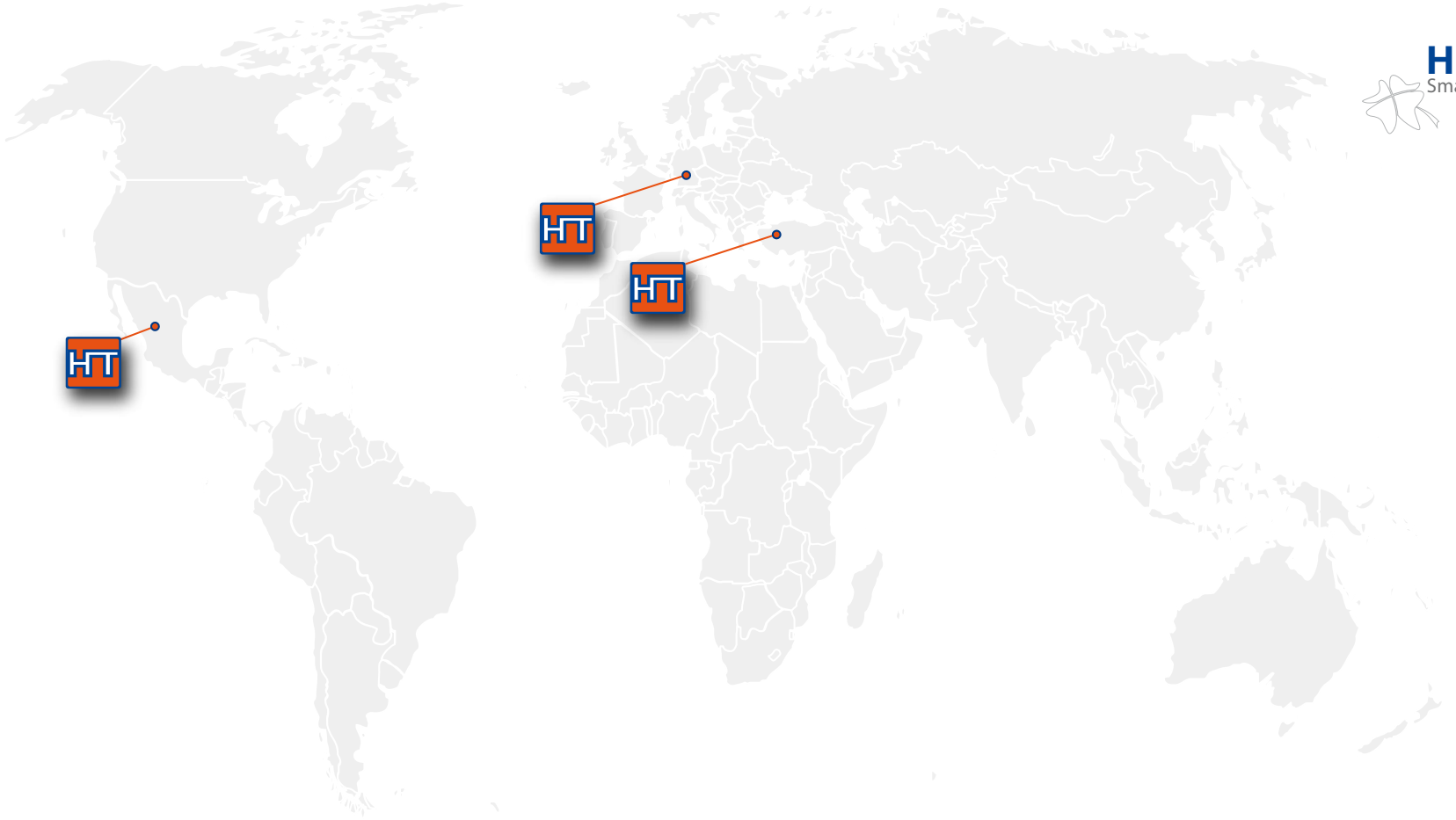






- The implants are supplied STERILE. They may be used only when the label on the outer packaging and also the inner packaging are intact. If the packaging is damaged or already open, the sterility of the implant is not guaranteed and the implant may not be used.
- The implants may not be used when the shelf life indicated has been exceeded.
- The implant may not be resterilized.
- Handle and store the implant components carefully. Damage to the implant can significantly reduce the stability and long-term stability of the implant system and can cause cracking and/or higher internal stresses, possibly resulting in the breakage of the implant.
- Storage of the implants and instruments should be at room temperature. Ambient influences, such as salty air, humidity, and chemicals, must not be allowed to act on the implants.
- Thorough inspection is recommended before operating in order to ensure that the instruments or implants have not been damaged during storage or previous procedures.





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